of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SONATA (zaleplon). SONATA is indicated for the short-term treatment of insomnia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SONATA (U.S. Patent No. 4,626,538) from American Cyanamid Co., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 13, 2000, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SONATA represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SONATA is 3,027 days. Of this time, 2,435 days occurred during the testing phase of the regulatory review period, while 592 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date on exemption under sectian 505(i) of the Federol Food, Drug, ond Cosmetic Act (the oct) (21 U.S.C. 355(i)) become effective*: May 2, 1991. The applicant claims May 16, 1991, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 2, 1991, which was 30 days after FDA receipt of the IND.

2. *The date the opplicotian was initially submitted with respect to the human drug praduct under sectian 505 of the act*: December 30, 1997. The applicant claims January 13, 1998, as the date the new drug application (NDA) for SONATA (NDA 20–859) was initially submitted. However, FDA records indicate that NDA 20–859 was submitted on December 30, 1997.

3. *The date the application wos appraved*: August 13, 1999. FDA has verified the applicant's claim that NDA 20–859 was approved on August 13, 1999.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,835 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by March 26, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 24, 2002. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above). Three copies of any information are to be submitted, except that individuals may submit one copy. Comments and petitions are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 28, 2001.

**Jane A. Axelrad,**

*Associote Director for Policy, Center for Drug Evoluotion and Reseorch.*

[FR Doc. 02–1925 Filed 1–24–02; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01E–0363]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; MIFEPREX

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for MIFEPREX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

**FOR FURTHER INFORMATION CONTACT:** Claudia Grillo, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product MIFEPREX (mifepristone). MIFEPREX is indicated for the medical termination of intrauterine pregnancy through 49 days pregnancy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for MIFEPREX (U.S. Patent No. 4,386,085) from the Population Council, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 2, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of MIFEPREX represented the first permitted commercial marketing or use of the product. Shortly thereafter,

Commissioner of Food and Drugs (the Commissioner) to implement general powers (including conducting research) to effectively carry out the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical device usage that are not foreseen or apparent during the premarket notification and review process. FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch Reporting Systems using FDA Forms 3500 and 3500A (OMB Control No. 0910–0281).

FDA received a 1-year OMB approval on February 5, 2001, to implement Emergency Health Surveys (since that time, renamed "Rapid Response Surveys"), via a series of surveys, thus implementing section 705(b) of the act and the Commissioner's authority as specified in section 903(d)(2) of the act. To date, FDA has initiated one Rapid Response Survey (66 FR 49391, September 27, 2001), with two more in development. FDA is now seeking OMB clearance to continue collecting this information. Participation in these surveys has been, and will continue to be, voluntary. This request covers Rapid Response Surveys for general type medical facilities and specialized medical facilities (those known for cardiac surgery, obstetric/gynecological services, pediatric services, etc.), and health professionals, but more typically risk managers working in medical facilities.

FDA currently uses the information gathered from these surveys to quickly obtain vital information from the appropriate clinical sources so that FDA may take appropriate public health or regulatory action. FDA projects 10 rapid response surveys per year with a sample of between 50 and 200 respondents per survey.

In the **Federal Register** of September 27, 2001 (66 FR 49391), the agency requested comments on the proposed collection of information. No comments were received.

FDA originally estimated the burden of this collection to be 2 hours per survey. However, FDA is revising the estimated burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|
| 200 | 10 (maximum) | 2,000 | .5 | 1,000 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the maximum sample size per questionnaire that FDA could analyze in a timely manner. The annual frequency per response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while another respondent may be contacted several times—depending on the medical device under evaluation. Based on the questions developed for the one survey that has been conducted, and for the two under development, it is estimated, given the expected type of issues that will be addressed by the surveys, that at a maximum it will take 30 minutes for a respondent to gather the requested information and fill in the answers.

Dated: January 17, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–1928 Filed 1–24–02; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 00E–1234]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; SONATA

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for SONATA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

**FOR FURTHER INFORMATION CONTACT:** Claudia V. Grillo, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all